

PATENT COOPERATION TREATY PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty) (PCT Article 36 and Rule 70)

REC'D 30 MAY 2005

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Applicant's or agent's file reference AY/MT/gs/2004.1317	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/SG2004/000173	International filing date (day/month/year) 9 June 2004	Priority date (day/month/year) 9 June 2003	
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61K 38/21; A61P 11/00			
Applicant GENOME INSTITUTE OF SINGAPORE et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 08 April 2005	Date of completion of the report 16 May 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer NICOLE HOWARD Telephone No. (02) 6283 2245

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000173

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-32	YES
	Claims 33-39	NO
Inventive step (IS)	Claims 1-32	YES
	Claims 33-39	NO
Industrial applicability (IA)	Claims 1-39	YES
	Claims NONE	NO

2. Citations and explanations (Rule 70.7)

CITATIONS

D1 TAN, E.L.C. et al., "Inhibition of SARS Coronavirus Infection In Vitro with Clinically approved Antiviral Drugs", Emerging Infectious Diseases, (April 2004), Vol. 10, No. 4, pages 581-586

D2 CINATL, J. et al., "Treatment of SARS with Human Interferons", The Lancet, (26 July 2003), Vol. 362, pages 293-294

D3 US 4 588 585 A (MARK, D.F. et al.) 13 May 1986

D4 US 6 350 589 B1 (MORRIS, J. P. et al.,) 26 February 2002

D5 Healthopedia.com Drugs Information, Interferons, Alpha (Systemic), Date revised 09/12/2001, Retrieved on 29 September 2004 from the Internet: [URL: http://www.healthopedia.com/drugs/detailed/interferons-alpha](http://www.healthopedia.com/drugs/detailed/interferons-alpha)

EXPLANATIONS

D3 teaches recombinant cysteine depleted interferon-B muteins also known as IFN B-1b and marketed as Betaseron/Betaferon. D4 teaches compositions of highly-purified natural mixtures of type 1 interferon derived from leukocytes (human leukocyte IFN α), formerly known as Omniferon and presently marketed as Multiferon. D5 teaches IFN α -n1 and IFN α -n3 marketed as Wellferon and Alferon respectively. Claims 33-39 are directed to kits comprising these interferon subtypes and instructions for using them in the treatment of SARS. While D3-D5 do not disclose the treatment of SARS, the mere inclusion of instructions is not considered to be limiting of the claim. Therefore D3-D5 deprive claims 33-39 of novelty and an inventive step.

D1 teaches the use of IFN α -n1, IFN α -n3, human leukocyte IFN α and IFNB-1b in the inhibition of SARS-coronavirus infection of Vero cells (a specific line derived from the kidney of African Green monkeys) in vitro and is relevant to claims 7-17, 19-27 and 29-39. D2 teaches the use of IFNB-1b in the inhibition of SARS-coronavirus infection of FFM-1 and Hong Kong clinical isolates of SARS-coronavirus in vitro and is relevant to claims 7-17, 19, 21-27, 29 and 31-39. Neither citation directly teaches the efficacy of these agents in the treatment of a patient with SARS, nor are they necessarily predictive of success and therefore are not relevant to the remaining claims.

However, D1 and D2 are both published prior to the international filing date but later than the priority date claimed and therefore do not deprive any of the claims of novelty or an inventive step.

Claims 1-39 are all considered industrially applicable.